CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In a 25-year old male military member diagnosed with low back pain, which characteristic is a stronger predictor of high opioid use, a prior history of opioid use or initial Oswestry Low Back Pain Disability Questionnaire score?

AUTHOR

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CLINICAL SCENARIO

A patient you have treated before or has received therapy before for another issue comes in with complaints of LBP. It becomes known that this patient has used opioids in the past and had become dependent on them for relief of his or her pain. You test and evaluate this individual and discover that he currently scores poorly on the ODI, which makes sense given his current reported level of function. As not to bias your opinions about this patient, and in order to most effectively educate and treat his back pain, you wish to understand whether his prior history with opioids or his baseline disability score is a higher predictor of future opioid usage. Or potentially if neither is a strong predictor. Understanding these relationships will help to guide both your patient education with regards to pain management, as well as your justification for patient referral should you suspect opioid use is becoming a problem in the future.

SUMMARY OF SEARCH

- 3 electronic databases were searched and 8 studies were found that met the inclusion and exclusion criteria, including 6 prospective cohort studies, 1 retrospective cohort study, and 1 cross-sectional cohort study with retrospective analysis. Two of the highest quality studies, based upon criteria from the Quality Assessment Checklist, were selected for closer review and analysis.
- No studies directly explored whether of a history of opioid use or baseline ODI scores were predictive of future opioid use. No studies explored either of these factors in a military population.
- Increased opioid use at baseline as well as increased perceived disability at baseline in patients with acute low back pain are predictive of long-term opioid use.
- Severe baseline ODI scores are predictive of long-term continued disability in chronic low back pain patients receiving conservative treatment.

CLINICAL BOTTOM LINE

There is currently no direct evidence that demonstrates the predictive ability of a prior history of opioid use or baseline Oswestry Disability Index scores in predicting future opioid use in patients with low back pain. Because of the severity of complications associated with chronic opioid use, it is important for therapists to be able to recognize and screen for factors that may implicate increased risk for long-term use. Evidence seems to suggest that baseline severe perceived disability and/or increased opioid use at baseline may be predictive of prolonged disability and/or long-term opioid use. It is thusly advised that clinicians screen for both perceived disability and opioid use at baseline to better understand their patient's risk for continued use, and in order to better inform their decisions with regards to education about alternative forms of pain management or the need for referral.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Military Veteran* "armed forces" "low back pain" LBP Lumbago	Opioid* Narcotic* History "history of"	"oswestry low back pain disability questionnaire" "oswestry disability index" ODI	Opioid* Narcotic* Predict/s Predictor/s

Final search strategy:

For PubMed

1. Military OR Veteran* OR "armed forces"
2. Low Back Pain [MeSH Terms]
3. "low back pain" OR LBP OR Lumbago
4. Opioid* OR Narcotic*
5. History OR "history of"
6. "oswestry low back pain disability questionnaire" OR "oswestry disability index" OR ODI
7. predict OR predicts OR predictor OR predictors
8. #4 AND #5
9. #2 OR #3
10. #1 AND #2 AND #6 AND #7 AND #8 – **0 results**
11. #1 AND #3 AND #6 AND #7 AND #8 – **0 results**
12. #1 AND #2 AND #4 AND #6 AND #7 – **0 results**
13. #1 AND #3 AND #4 AND #6 AND #7 – **0 results**
14. #1 AND (#2 OR #3)
15. #14 AND #4 - **43 results**
16. #1 AND #6 AND #7 - **11 results**
17. #1 AND #4 AND #7 – **103 results**
18. Opioid* OR Narcotic* [MeSH Terms]
19. Predict [Title] OR predicts [Title] OR predictor [Title] OR predictors [Title]
20. #1 AND #18 AND #19 – **21 results**
21. #9 AND #4 AND #6 AND #7 – **3 results**
22. #9 AND #4 AND #6 – **86 results**
23. #9 AND #4 AND #7 – **52 results**
24. #9 AND #6 AND #7 – **98 results**

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
PubMed (No single search strategy was optimal. Search result totals are the combination of multiple relevant search strategies: #16, #17, #23, #24)	**264**	**182 –** See #17-#20; Revised total from: #16, #20, #23, #24
CINAHL (No single search strategy was optimal. Search result totals are the combination of multiple relevant search strategies)	**245**	**156** (Specified [TI Title] for: predict OR predicts OR predictor OR predictors, and then for "oswestry low back pain disability questionnaire" OR "oswestry disability index" OR ODI on a search strategy that yielded 140 initial

Embase PICO (Military/Veteran search population was dropped for EMBASE PICO search strategy to increase yield of results. "low back pain" OR LBP OR Lumbago was used as the search population	**96**	results. The revised number yielded were 47, and then 4 respectfully) **57** (Specified the Study Design: Prospective Study; Retrospective Study; Randomized Control Trials; Cohort Analysis)

Note: Total number of results does not take into account duplicate studies

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Randomized Control Trials (RCTs), Controlled Trials, Uncontrolled Trials, Prospective Studies, Cohort Studies, Retrospective Cohort Studies • Published in English • Studies that measure low back pain related disability using the Oswestry Low Back Pain Disability Questionnaire or Oswestry Disability Index • Studies that predict opioid use and/or include study participants who have low back pain and take opioids • Only studies published since 2000
Exclusion Criteria
• Not published in English • Abstracts, conference proceedings, letters to the editor, dissertations, narrative review articles

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Risk of bias (quality score)	Level of Evidence	Relevance	Study design
Thielke et al. (2017) [1]	Quality Assessment Checklist (QAC): Low Risk	Prognosis 1b	Mod	Prospective Cohort Study
Villavicencio et al. (2017) [2]	QAC: Mod Risk	Prognosis 1b	Low	Prospective Cohort Study
Lee et al. (2014) [3]	QAC: Mod Risk	Prognosis 1b	Low	Prospective Cohort Study
Ruiz et al. (2014) [4]	QAC: Mod Risk	Prognosis 2b (Downgraded due to study design)	Low	Cross-Sectional Cohort Study (with Retrospective Analysis)
Van Hooff et al. (2014) [5]	QAC: Low Risk	Prognosis 1b	Mod	Prospective Cohort Study
Asher et al. (2016) [6]	QAC**:** Low Risk	Prognosis 1b	Low-Mod	Prospective Cohort Study
Hellum et al. (2012) [7]	QAC: Low Risk	Prognosis 2b (Downgraded due to study design)	Mod	Retrospective Cohort Study
Franklin et al. (2009) [8]	QAC: Low Risk	Prognosis 1b	Mod	Prospective Cohort Study

BEST EVIDENCE

The following 2 studies were identified as the 'best' evidence and selected for critical appraisal. Rationale for selecting these studies were:

- Van Hooff et al. (2014) [5]
  - Prospective Cohort Study (vs. Retrospective)
  - Large Sample Size (n=524)
  - Relatively younger study population (45.4±9.6 years)
  - Study explored the predictors of successful clinical outcome for patients with chronic low back pain
  - Study explored the predictive effects at 1-year with conservative treatment
  - Primary outcome measure used in this study was the ODI
  - Predictive model developed using random sampling of the study population
  - Only study which validated its prognostic findings in a secondary population
- Franklin et al. (2009) [8]
  - Prospective Cohort Study (vs. Retrospective)
  - Large Sample Size (n=1843)
  - Relatively younger study population (All <55; 32.7% 24-34 years old)
  - Study explored the predictors of long-term opioid use in patients with low back pain
  - Study explored the predictive effects over 1-year
  - Younger, generally active, mostly male (68%) study population more closely mimics the population of interest
  - Study participants initially injured while working, which more closely mimics potential MOIs in the population of interest; Decreased potential for bias due to all subjects entering the study at an early stage of their condition
  - Study also made use of available detailed pharmacological data to examine the relationship between

opioid dosing and long-term use

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of "Opioid Use for Chronic Low Back Pain A Prospective, Population-based Study Among Injured Workers in Washington State, 2002-2005" by Franklin et al. (2009)

Aim/Objective of the Study/Systematic Review:

The purpose of this study was to prospectively examine the predictors of long-term opioid use, examine prescription opioid use, and explore the associations between opioid use, pain and function in a cohort of workers diagnosed with acute low back pain [8].

Study Design

- This study was a prospective cohort study in a population of Washington State workers with acute low back pain.
- **Blinding:** No explicit mention of blinding or concealment of the study participants or assessors was provided in this study; Study participants were notified of the study purpose and all gave their informed consent to participate, so it can be assumed that they were not blinded; It should be mentioned however that opioid and other drug prescription data was not collected during study phone interviews, and was instead collected with a review of the participant's medical workers compensation database.
- **Outcomes:** Alcohol Use Disorders Identification Test (Baseline Interview); Numeric Pain Rating Scale (Baseline Interview, 12-month follow-up); **Roland-Morris Disability Questionnaire** (Baseline Interview, 12-month follow-up); 3-items from the Pain Catastrophizing Scale (Baseline Interview); 1-item from the Vermont Disability Prediction Questionnaire (Baseline Interview); 2-items from the Fear-Avoidance Beliefs Questionnaire (Baseline Interview); SF-36 v2 Mental Health scale (Baseline Interview**); Back Injury Severity** (Baseline); **Opioid Use** (Assessed at each 3-month quarter of the 12-month period)
    - **Bolded** outcomes are related to the CAT PICO; These are described in more detail below

Setting

This prospective study explored a population of Washington State workers in the United States; It can be assumed that participants in this study came from varied communities and sociodemographic backgrounds, although this was not explicitly stated. Data analysis was most likely performed in a laboratory or academic setting.

Participants

- **N** = 1843
- **Diagnosis:** Acute low back injury
- **Eligibility Criteria:** Age ≥ 18 years; 4 or more days of lost time from work secondary to injury; At least 1 day of wage replacement compensation; Recent diagnosis and claim filed for low back pain
- **Recruiting Methods:** Potential participants were screened weekly using the Washington State Department of Labor and Industries State Fund claims database; Potential participants meeting the eligibility criteria were contacted to establish interest in participating in the study
- **Sample Type:** Purposive sample of Washington State workers filing recent medical claims for low back pain
- **Key Demographics**
    - Mean Age: 39.4 years
    - Gender: Males (68%); Females (32%)
    - No significant difference in sex, age, baseline Roland-Morris Disability Questionnaire score, injury severity, or opioid use in the first quarter was observed between those who did and did not (n=1296) complete the follow-up interview at 12 months
- **Dropouts:** 547 participants (~30%) dropped out of the study between baseline and 12-month follow-up; 1296 participants were available and participated in follow-up

Intervention Investigated

Control

- This was not an intervention study, and thus no control group was present

Experimental

- **Methods/Data Collection:** Potential study participants were identified through the weekly monitoring of the *Washington State Department of Labor and Industries State Fund* claims database. These potential participants had recently filed a medical claim for low back pain. After initial screening, potential subjects were reached out to by phone to establish interest for participation in the study. Baseline data collection was collected via computer assisted phone interviews, which gathered information about sociodemographic status, pain, function, history of prior back pain, medical status, whether or not the participant sought chiropractic care, tobacco and alcohol use, and psychosocial factors. Baseline injury severity and opioid prescription information was collected from the participant's Washington State medical records database. Follow-up interviewing was conducted at 1-year post-baseline interviewing. Measures of pain intensity and functional status were assessed with telephone follow-up. Analysis of opioid prescription information and injury severity over the 12-month period were assessed with a review of the participant's Washington State medical records database. Collected information was then statistically analyzed for significance and predictive ability as below.
- **Analyses:** Trends in opioid dosing were analyzed with linear modeling; To determine which factors were associated with 12-month use, characteristics of participants remaining on opioids at 12-months were compared to those who received opioids during the first 3-months, but discontinued use before 12-months; Logistic regression of bivariate association between baseline characteristics of study participants and 12-month opioid use was used to determine which of these factors were significantly related to 12-month opioid use; Variables found to be significantly associated with 12-month opioid use were then analyzed using multivariate logistic regression modeling; Multivariate logistic regression was used as a way to control for the other baseline factors found to be significantly associated with 12-month opioid use; Both univariate and multivariate analyses were performed using 95% confidence intervals; Software used for the statistical analyses was not disclosed.

Outcome Measures

- **Roland-Morris Disability Questionnaire** [10]**:** The Roland-Morris Disability Questionnaire is a validated self-report measure of disability and function in patients with nonspecific low back pain; Max = 24 (Max disability/Reduced Function); Range 0-24; Administered by "Interviewers" (No further information regarding who the "Interviewers" were was discussed); Assessed during both baseline and 12-month follow-up with computer-assisted telephone interviewing
- **Back Injury Severity** [11]: Measure used to analyze injury severity based upon a system used in a previous study in patients with low back pain [11]; Max = knee or ankle reflexes absent, injury-related bladder complaints, or motor abnormalities; Range (mild sprain or strain or minor physical examination findings ←→knee or ankle reflexes absent, injury-related bladder complaints, or motor abnormalities); Obtained by "trained nurses" through a review of the participant's initial medical records
- **Opioid Use:** Assessed for each 3-month quarter in the 12-months post-injury; No specific mention of whom reviewed the medical billing database was given; Number of opioid prescriptions filled per quarter, along with the morphine equivalent dose (MED) per quarter were collected from information in the database

Note: Additional outcome measures were assessed at baseline, and with 12-month follow-up, however these measures did not significantly relate to the CAT PICO question, and are thus not addressed further

Main Findings

- Of the 1843 participants whom met the inclusion criteria and participated in the study, 781 (42%) received at least one opioid prescription in the 12-months post-injury
- 89% of those receiving an opioid prescription for low back pain filled that prescription within the first 3-months post-injury
- 16% of those receiving an opioid prescription for low back pain filled those prescriptions for all 12-months of the study (Chronic use)
- When comparing 12-month opioid users with 3-month opioid users, 12-month opioid users were found to fill ~3 times the amount of opioid prescriptions, 5.8 (SD=3.8), in the first 3-months vs. 2 (SD=1.7)
- When comparing 12-month opioid users with 3-month opioid users, 12-month opioid users were found to use ~5 times the amount of opioid, MED=2364mg (SD=4019), in the first 3-months vs. MED=465mg (SD=711)
- Mean MED increased in 12-month opioid users from MED=2364mg (SD=4019) at 3-months to MED=3824mg (SD=5998); P=0.01
- 26% of 12-month opioid users were found to incur a clinically significant improvement in pain scores from Baseline to 12-months; Baseline Pain rating mean score=7.7; 12-month pain rating mean score=6.8
- 16% of 12-month opioid users were found to incur a clinically significant improvement in physical function from Baseline to 12-months; Baseline mean RDQ=18.8; 12-month mean RDQ=17.5
- 12-month opioid users whom did not demonstrate clinically meaningful improvements in pain or function, statistically significant increases in MED from Baseline to 12-months were noted (P=0.01; P<0.01

respectfully)

Predictors of 12-month (Long-Term) Opioid Use

Domain (Baseline)	Univariate Odds Ratio (95% CI)*	Multivariate Odds Ratio (95% CI)*	p-Value
Pain (8-10)	21.22 (6.51-69.11)	9.41 (2.69-32.94)	<0.05
RDQ (18-24)	7.34 (3.59-14.99)	2.65 (1.20-5.87)	<0.05
Injury Severity (Radiculopathy)	5.39 (3.20-9.06)	3.17 (1.83-5.51)	<0.05
Prior Back Injury	2.93 (1.93-4.44)	2.40 (1.50-3.83)	<0.05
1st quarter MED (900-1799 mg)	6.20 (3.60-10.65)	4.01 (2.23-7.20)	<0.05
1st quarter MED (1800-3599 mg)	8.52 (4.59-15.80)	5.46 (2.82-10.58)	<0.05
1st quarter MED (>3600 mg)	11.56 (5.70-23.45)	6.25 (2.91-13.41)	<0.05
Chiropractor 1st Practitioner	0.29 (0.10-0.82)	0.29 (0.10-0.84	<0.05
High Catastrophizing (3-4)	4.75 (2.76-8.18)	2.11 (1.11-4.02)	<0.05
Low Recovery Expectations (0-6)	3.47 (2.12-5.67)	1.88 (1.09-3.24)	<0.05

*** = All values Statistically Significant**

Original Authors' Conclusions

- Only a small minority of workers who initially receive opioids for acute low back pain continue to use opioids at 12-months
- Long-term opioid use for the treatment of low back pain does not appear to be associated with clinically meaningful improvements in pain or function at 12-months
- There exists a strong predictive relationship between the amount of opioids used within the first 3-months of low back injury, and continued use at 12-months
- "There is a clear need for closer scrutiny and improved management of opioids when used long-term for noncancer chronic conditions such as chronic back pain" (pg. 750)

Critical Appraisal

Validity

I evaluated the study quality of this prospective cohort study using the Quality Assessment Checklist as proposed in the Jewell textbook [12]. Overall, this study received a score of a relative low risk for bias. Strengths of this study that improved its risk for bias included the operationally defined sample, large sample size, subjects entering the study at relatively the same early stage of their condition, a sufficient study time-frame of 12-months, operationally defined outcome criteria, inclusion of subgroups for whom outcomes could differ based upon findings from multivariate regression analyses, and inclusion of separate sub-group analyses that accounted for these subgroups. Use of both univariate and multivariate regression analyses in the determination of baseline predictors of 12-month opioid use was another strength of this study, as controlling for confounding variables (i.e. age, sex, function, pain, and injury severity) improves the interval validity of the study results. Inclusion of baseline questions and outcome measures, which have been shown to be reliable predictors of long-term disability, also improves the internal validity of the study findings. While the participant study sample varied some in terms of age, sex, race, and educational level limiting the internal validity of the study, this somewhat mixed demographic improves the generalizability of the study results to subsequent populations. However, it should be noted that the degree to which these study results are generalizable beyond

the workers compensation population is still questionable.

Limits to study quality include the study population being slightly dissimilar to the population from which they were drawn (i.e. Slightly older [39.4 vs. 38.2], Increased number of females [32% vs. 26%], Increased workers receiving wage replacement at 12-months [13.8% vs. 11.3%]), the lack of blinding/concealment that occurred in both study participants and assessors, and the fact that the study investigators did not confirm their findings in a subsequent population. However, because the outcome measures included and analysed in this study were either patient self-report measures or objective data collected from a medical database, it is less likely that this lack of blinding/concealment had any significant effect on the risk for bias in this study. Replication of prognostic findings in subsequent populations is also quite uncommon in these types of studies, so the lack of confirmation of findings is unsurprising.

Interpretation of Results

From Table 1 (pg. 746), clear correlations between the length of opioid use and the mean amount of opioids used per participant per quarter can be observed. While statistical analyses are not displayed in the table, it is very clear that there is a linear relationship that exits between individuals who use opioids for longer periods of time, and the amount of opioids they use. This data also seems to suggest that individuals whom use higher amounts of baseline opioids tend to go on to use opioids for a longer periods, compared with those using less opioids at baseline. Another interesting trend to note is that in participants using opioids for 6 and 9 months, there exists a reduction in opioid use between the previous quarter and the final quarter. This seems to suggest that in individuals whom use opioids for 6 and 9 months, there is a tapering down of opioid use between the 3-6 months time period, and 6-9 months respectfully. This trend was not observed in those individuals using opioids for all four quarters (12-months). In this group, consistent and linear increases by an average MED per quarter of 487mg can be observed from Baseline to 12-months. In fact, between 9 and 12-months there existed the largest jump of all, 747 mg, which seems to suggest individuals whom use opioids for longer periods of time may in fact be at higher risk for complications secondary to the higher mean use.

From Table 2 (pg. 746), a clear linear trend exists between baseline MED opioid use, and MED opioid use at 12-months. The data suggests that the amount of opioids used during the first quarter (first 3-months) correlates with the amount of opioids used at 12-months. While one cannot use this information for predictive purposes, it is apparent that higher baseline opioid use is associated with higher 12-month opioid use, and vice versa.

From Table 3 (pg. 747), there are several things to note. Data suggests that in the majority of participants taking opioids for 12-months, the majority do not improve in either pain or function in a clinically meaningful way over the course of those 12-months (i.e. ≥30%). Data also seems to suggest that aside from a small number of individuals whom improved ≥30% on the RDQ (14 participants), mean MED per quarter appears to rise linearly between the 1st and 4th quarters in these individuals regardless of changes in perceived pain or reductions in perceived function.

From Table 4 (pg. 747), one can explore the trends in individuals taking high doses of opioids (i.e. ≥120mg/day) at 12-months. In the majority of these individuals, 89%, took higher doses (MED/day) of opioids at 12-months compared with baseline. Non-clinically significant differences in pain and function scores between baseline and 12-months seem to suggest that in individuals taking higher doses of opioids at 12-months, increases in MED/day do not correlate with improvements in pain or function. When combined with the results in Table 3, this seems to suggest that long-term opioid use (12-months) does not result in clinically meaningful changes in pain or function, and thus may not be an appropriate intervention for LBP patients in the long-term.

Table 5 (pg. 748,749), explores the baseline predictors of long-term (12-month) opioid use. Both univariate and multivariate predictive analyses of odds ratios were performed on this data set. The multivariate model controlled for the following variables: age, sex, function, pain, and injury severity. Use of this model as a predictor of long-term opioid use is comparatively more useful secondary to its ability to improve the internal validity of the results. Examining the multivariate odds ratios, it is apparent that initial pain scores >5, RDQ scores >18, radiculopathy, having a previous back injury, MED in the first 3-months >900 mg, Catastrophizing scores between 3-4, and low recovery expectations are all statistically significant predictors of long-term opioid use. In examining the odds for using opioids at 12-months, it is apparent that of these domains, worse baseline pain (5-7 or 8-10), worse injury severity denoted by signs of radiculopathy, and increased opioid use (900-1799mg, 1800-3599mg, or >3600mg) seem to be the strongest predictors of 12-month opioid use. Respectfully, the odds ratios of these domains were 5.88, 9.41, 3.17, 4.01, 5.46, and 6.25. In examining the precision of these predictors, some disparities are apparent. Wide confidence intervals for baseline pain scores of either 5-7 or 8-10 reduce the precision of these findings, and thus call into question the accuracy of using baseline pain scores in predicting long-term opioid use. Confidence intervals for both radiculopathy and all 1st quarter MED values are relatively narrow, thus presenting evidence that it may be more accurate to use injury severity or baseline MED use >900 mg/quarter as predictors of long-term opioid use. The domains of both being Hispanic and receiving Chiropractic care as your first intervention both demonstrated statistically significant odds ratios of <1, signifying that the odds of using opioids at 12-months in individuals with these domains is less than that of individuals without these domains. Confidence intervals in both domains were relatively narrow with multivariate analysis, thus identifying being Hispanic and receiving chiropractic care as accurately predictive of reduced likelihood for opioid use in 12-months. Higher baseline RDQ scores (i.e. >18)

signifying increased self-perceived disability also displayed relatively strong predictive ability for continued opioid use at 12-months, with an odds ratio of 2.65 in multivariate analysis. This finding suggests that clinically significant perceived disability may be predictive of long-term opioid use in individuals receiving at least one opioid prescription for acute low back pain. All analyses were performed using a P-value of <0.05.

Applicability of Study Results

This study was moderately relevant to my clinical question as it did explore the effects of opioid use in predicting long-term (12-month) opioid use in a cohort of LBP patients, however it did not directly explore whether or not a prior history of opioid use was predictive of long-term opioid use. Some of the issues limiting the applicability of the study findings to the clinical question population include the mean age of study participants (39.2 years) compared with the clinical question age of 25 years. The study population also did not include any military participants. The study demographic was also mixed in gender, with 68% of the participants being male compared with the specific male gender noted in the clinical question.

In exploring the breakdown of Washington State jobs, it is apparent that many of the jobs are quite active including wildlife fire fighters, construction labourers, and farm workers [13]. While more sedentary state jobs do exist, and while the breakdown of jobs held by the participants in this study was not disclosed, the potential for lower back injury with higher activity jobs would more closely mimic the potential injuries sustained with military training/service, thus increasing the external validity of the study findings to the clinical question population [13].

While the ODI was not assessed in this study, the RDQ was. This measure is also a valid and reliable assessor of self-reported disability in low back pain patients [10]. Moreover, a 2016 meta-analysis of the measurement properties between the RDQ and the ODI found that both measures were accurate assessors of physical function in patients with non-specific low back pain, and that neither measure should be preferred over the other [14]. To that end, while the direct evidence was not assessed in this study, severe baseline RQD scores (≥ 18) were found to be predictive of long-term opioid use. It could be assumed then, that severe baseline ODI scores would also be predictive of long-term opioid use, however these assumptions require further study for validation. Therefore if the military patient described in the PICO question does score highly on his baseline ODI and was taking opioids at baseline, it may be more likely that this individual would continue to use opioids long-term. And so thought should be given to appropriate education for pain management in this individual. Both the RDQ and the ODI are relatively simple and efficient patient self-report measures, which are easily implemented in the clinical setting. These characteristics, combined with the ease of interpretation of their results make them highly feasible for use in predicting long-term opioid use.

While a prior history of opioid use was not assessed, there exists a clear correlation between early opioid use and long-term opioid use (12-months) in patients with LBP. While the majority of study participants prescribed opioids for LBP did not go on to use opioids at higher doses or long-term, larger amounts of opioids used during the first 3-months after onset of LBP were significantly predictive of long-term opioid use. As it applies to the clinical scenario, if this military patient was taking higher doses (i.e. >900 mg/quarter) of opioids when presenting to the clinic, it may be more likely that this individual would go on to use opioids long-term (12-months). These implications should thus be considered and monitored as you continue to treat and educate this patient with regards to pain/symptom management. Patients are not always aware of the amount of opioids they are taking or being prescribed, so information about opioid dosing is relatively less accessible in the clinical setting. MED/quarter can be estimated by reviewing the patient's prescribed dose (opioid mg/day) and multiplying that number by ninety (~3 months). While this would give the clinician a rough idea of about how much opioid medication the patient will be taking over the next 3 months, it is not a direct measurement, and so the validity of using those estimations in applying these study findings could be called into question. A dichotomous yes/no on whether or not the patient used opioids in the past would be much more easily assessed in the clinic, however further investigation needs to be made that directly addresses the validity of using a history of prior opioid use in predicting long-term or higher dose opioid use in the LBP population.

(2) Description and appraisal of "Predictive factors for successful clinical outcome 1 year after an intensive combined physical and psychological programme for chronic low back pain" by van Hooff et al. (2014)

Aim/Objective of the Study/Systematic Review:

The purpose of this study was to determine the factors that predicted successful long-term (12-month) outcome in a cohort of chronic low back pain patients undergoing a two-week intervention designed to address both the physical and cognitive-behavioural factors implicated with chronic low back pain [5].

Study Design

- This study was a prospective cohort study in a population of chronic low back pain patients referred to an outpatient specialized spine center
- **Blinding:** No explicit mention of blinding or concealment of the study participants or assessors was provided in this study, and it can be assumed from the study design that neither occurred
- **Outcomes:** Medical History (Baseline); Pain History (Baseline); Pain Score (Baseline); Consumption of Pain Medication Yes/No (Baseline); Employment Status Yes/No (Baseline); **Oswestry Disability Index** (Baseline, 2-weeks, 12-months); Numeric Rating Scale (Baseline, 2-weeks, 12-months); Zung Self-Rating Depression Scale (Baseline, 2-weeks, 12-months); Pain Self-Efficacy Questionaire (Baseline, 2-weeks, 12-months); Pain Catastrophizing Scale (Baseline, 2-weeks, 12-months); Tampa Scale for Kinesiophobia (Baseline, 2-weeks, 12-months)
    - The **Oswestry Disability Index** was the main outcome measure used in this study, and is the most relevant to the CAT PICO; This measure is described in more detail below

Setting

This study was performed in the Netherlands; The 2-week CPP program (discussed further below) was delivered in a community hotel setting; Although not explicitly mentioned, data analysis was most likely performed in a hospital or academic setting based upon study description.

Participants

- **N** = 524
- **Diagnosis:** Chronic Low Back Pain
- **Eligibility Criteria:** Low back pain for at least 6-months; Aged between 18-65 years; Participants had to be willing to change their behaviours; Participants had to be willing to partake in a 2-week physical and cognitive-behavioural program; Participants could not be candidates for spinal surgery or invasive forms of pain management
- **Recruiting Methods:** Potential participants were referred to a third party outpatient hospital specializing in spinal care; Potential Participants were screened based on inclusion/exclusion criteria, and those who met the study standards were asked whether or not they wished to participate in the study
- **Sample Type:** Sample of convenience based upon individuals referred to this outpatient facility who met the assessors inclusion/exclusion criteria
- **Key Demographics**
    - Mean Age: 45.4 years
    - Gender: Males (42%); Females (58%)
    - Mean Duration of Low Back Pain: 12.5 years
    - No significant difference in baseline characteristics or baseline outcome measure scores (including the Oswestry Disability Index) were found between those who completed both baseline and follow-up assessment, and those who did not complete follow-up assessment
- **Dropouts:** 67 participants (~13%) had missing data or dropped out of the study between baseline and 12-month follow-up; The Multiple Imputation (MI) technique was used to replace missing values in these individuals with calculated values based upon the available data. Thus all 524 participants were also assessed at follow-up

Intervention Investigated

Control

- This was not an intervention study, and thus no control group was present (although there was an intervention implemented as described below)

Experimental

- **CPP Program Methods** [5,15]**:** This program incorporates a multi-disciplinary conservative approach to treating chronic low back pain; Disciplines including physical therapy, occupational therapy, and psychology provide over 100 hours patient treatment and education; The intervention took place over the course of 2-weeks, and consisted of ~40 hours of cognitive-behavioural training, ~30 hours physical activities (including stretching and exercises), and ~10 hours on education (ex. Relaxation Techniques); A substantive description of the CPP program methods were not provided in this study as its effects were not the focus or purpose in this study

- **Methods/Data Collection:** Patients in this study were recruited from a cohort of individuals with chronic low back pain as described above; Various self-reported outcome measures were conducted at baseline as described above, the most relevant of which was the Oswestry Disability Index; Participants then took part in the CPP Program as described above; At the end of the two-week program Oswestry Disability Index scores were reassessed; At 12-months, Oswestry Disability index scores were assessed one last time to determine long-term perceived disability; Collected information was then statistically analyzed for significance and predictive ability as below
- **Analyses:** Baseline characteristics of responders and non-responders were compared using Chi square tests and Student's t-tests for categorical variables and continuous variables respectfully; Successful patient outcome at 12-month follow-up on the Oswestry Disability Index was determined to be a score of 22, whereby patients with scores ≤22 were considered to have achieved a "successful outcome" [16]; Dichotomized groups (Successful patient outcome; Failed patient outcome) were then compared with baseline characteristics; Pearson's correlation coefficients were then used to identify which baseline characteristics were significantly associated with successful (i.e. ≤22 on the Oswestry Disability Index) patient outcome; These factors were then analysed using a univariate logistic regression analysis to determine which of these factors were potentially predictive of successful outcome; The study population was then randomly divided into two equal groups (n=262) to allow for validation of the study findings and final prediction model using a subsequent population; Multivariate logistic regression analysis was then used to control for the effects of other baseline characteristics found to be significantly associated with successful 12-month outcome; 95% Confidence intervals and p values <0.05 were used for this analysis; After determination of statistically significant predictor factors using the final multivariate prediction model, these factors and the final prediction model were then validated using the remaining randomized 50% patient population (n=262); All data analysis was performed using SPSS version 18.0; Missing data were accounted for using the MI-technique as described above.

Outcome Measures

- **Oswestry Disability Index** [17]: Patient self-report measure validated in low back pain patient samples, which measures the impact of LBP on perceived physical functioning and disability; Max = 50 (maximally disabled); Range 0-50; Specifics regarding who administered the outcome measures were not detailed, and thus blinding cannot be determined, although it is unlikely; Although not explicitly stated, it can be inferred that baseline ODI scores were recorded at the outpatient hospital on assessment, 2-week ODI scores were assessed at the hotel site after the CPP program, and 12-month ODI was also assessed at the hospital setting during 12-month follow-up assessment

Note: The main outcome measure used during this study and for analysis purposes was the Oswestry Disabiiity Index; This measure was the most relevant to the CAT PICO and was thus included for further description; Other outcome measures were assessed in this study, however due to irrelevance to the CAT PICO they were not expounded upon here

Main Findings

- The mean baseline ODI perceived disability score for participants was found to be 41.4 (SD=14.1), indicative of the most severe scoring criteria on the ODI [16,18]
- The majority of patients improved from baseline to 12-month follow-up on perceived disability (i.e. ODI score), with a mean improvement of 31% noted amongst participants
- 157 participants (~30%) with baseline ODI scores >22, signifying increased levels of disability compared with healthy populations, improved their scores from >22 to ≤22 from baseline to 12-month follow-up
- All the following baseline categorical variables and baseline continuous variables were found to be significantly associated with successful patient outcome:

Baseline Categorical Variables	Total (n=524)	Successful Outcome Participants (n=217)	Failed Outcome Participants (n=307)	p-Value
Employment Status (Yes)	356 (67.9%)	194 (89.4%)	162 (52.8%)	<0.001
Pain Medication (Yes)	454 (86.6%)	176 (81.1%)	278 (90.6%)	<0.05
Previous Back Surgery (Yes)	169 (32.3%)	54 (24.9%)	115 (37.5%)	<0.05

Baseline Continuous Variables	Mean Score (n=524)	Successful Outcome Mean Score (n=217)	Failed Outcome Mean Score (n=307)	p-Value
Age (years)	45.4 (±9.6)	43.7 (±9.2)	46.6 (±9.8)	<0.001
Duration of LBP (years)	12.5 (±10.8)	11.7 (±9.9)	13.0 (±11.3)	<0.001
Oswestry Disability Index Score	41.4 (±14.1)	33.7 (±13.1)	46.8 (±12.0)	<0.001
Zung Self-rated Depression Scale score	26.2 (±9.3)	24.4 (±9.9)	27.5 (±8.6)	<0.001
Numeric Rating Scale score	60.7 (±21.1)	56.4 (±22.2)	63.7 (±19.8)	<0.001
Pain Catastrophizing Scale score	22.9 (±8.9)	22.3 (±8.7)	23.4 (±8.9)	<0.001
Tamps Scale for Kinesiophobia score	39.6 (±6.4)	39.0 (±6.5)	40.0 (±6.4)	<0.001
Pain Self-efficacy Questionnaire score	32.4 (± 10.8)	36.3 (±10.1)	29.6 (±10.4)	<0.001

- Univariate regression modelling revealed that baseline age, previous back surgery, positive employment status, pain self-efficacy, and Oswestry Disability Index score were potentially predictive of successful 1-yeat outcome; Odds Ratio's and CI's for these findings were not provided
- The final multivariate prediction model found that both being employed at baseline and baseline ODI scores >22 were significantly predictive of successful 12-month outcome:

Baseline Domain (n=262)	Multivariate Odds Ratio (95% CI)*	p-Value
Oswestry Disability Index Score (>22)	0.94 (0.92-0.97)	<0.001
Employment Status (Yes)	3.61 (1.80-7.26)	<0.001

- The final prediction model was then validated in the subsequent population of randomized study participants (n=262) enrolled into the study:

Baseline Domain (n=262)	Multivariate Odds Ratio (95% CI)*	p-Value
Oswestry Disability Index Score (>22)	0.92 (0.89-0.94)	<0.001
Employment Status (Yes)	6.29 (1.96-13.70)	<0.001

*** = All values Statistically Significant**

Original Authors' Conclusions

- Chronic low back pain patients who are working and who are mild-moderately disabled are more likely to incur successful functional outcome with a 2-week multi-disciplinary conservative treatment approach (i.e. CPP program)
- Improvements to disability levels observed (ODI ≤ 22) in healthy adult populations is likely with these

participants at 12-months
- Small number of predictive indicators (n=2) makes for easy assignment of probable successful CLBP patients vs. probable 'failure' CLBP patients with a multi-disciplinary conservative treatment approach

Critical Appraisal

Validity

I evaluated the study quality of this prospective cohort study using the Quality Assessment Checklist as proposed in the Jewell textbook [12]. Overall, this study received a score of a relative low risk for bias. Strengths of this study that improved its risk for bias included the operationally defined sample, large sample size, a sufficient time frame during which to capture the outcome of interest (i.e. 12-months), the collection of at least baseline outcomes from all participants enrolled in the study, the operationally defined outcome criteria, inclusion of subgroups for whom outcomes could differ based upon findings from multivariate regression analyses, inclusion of separate sub-group analyses that accounted for these subgroups, and confirmation of the validity of the final logistic regression prediction model in a randomized secondary population of enrolled study participants (n=262). Confirmation of the study findings in a randomized 'new set of subjects' is a rare positive attribute in these kinds of prospective studies, and greatly improves the interval validity of the study findings. Although follow-up data was missing for 67 participants (~13%), use of MI technique to replace these missing values reduces the impact of the "drop-outs" on the interval validity of the study findings. Use of both univariate and multivariate regression analyses in the determination of baseline predictors of improved outcome was another strength of this study, as controlling for the effects of additional significantly related variables improves the interval validity of the study results. Use of previously validated patient self-report outcome measures in the CLBP population also helps to improve the interval validity of the study findings.

Limitations to study quality include an inability to determine whether or not the subjects were representative of the population from which they were drawn secondary to the exclusion of data for those who were not included in the study, the fact that study participants did not enter the study at an early stage of their condition, and the presumed lack of blinding/concealment that occurred in both study participants and assessors. Because the outcome measures included and analysed in this study were patient self-report measures, it is less likely that a lack of blinding/concealment had any significant effect on the risk for bias in this study While all study participants were considered to be chronic low back pain patients, the duration of symptoms varied considerable amongst the study participants (mean duration = 12.5 years [SD= ±10.8]). This finding, combined with the fact that some participants had received surgical intervention for CLBP symptoms (~32%), while others had not limits the homogeneity of the study population, reducing the studies internal validity. Potential selection bias that may have resulted from the participant recruitment methodology could have biased the results in favour of the study population, reducing the generalizability of the study findings to subsequent populations. Specifics regarding the CPP program interventions were not included in this study, reducing the reproducibility of these interventions in future CLBP populations. And while the CPP program included a multidisciplinary conservative approach to treatment in CLBP patients, it is unclear if the potential predictors of successful patient outcome found in this study would be applicable to similar conservative treatment approaches.

Interpretation of Results

From Table 1 (pg. 107): It is clear that the demographic of this study was relatively mixed with 58% females, 68% employed at baseline, and with 32% having undergone surgery for LBP. The population was relatively younger than with other studies reviewed, with a mean age of 45 years (SD±9.6). These subjects had also been experiencing CLBP symptoms for an extended period of time (~13 years), and most reported the highest level of disability on the ODI at baseline [16,18].

From Table 2 (pg. 107): While most participants reported the most severe disability score at baseline, the majority had clinically significantly improved disability scores at 12 months. The mean ODI score went from 41.4 at baseline, to 27.6 at 12-months for the entirety of the study population (n=524). This drop of nearly ~14 points (~28%) on the ODI represents a clinically meaningful improvement, as an MCID of 10 points has been established for the ODI in patients with CLBP [19]. These findings may implicate the effectiveness of a conservative multi-disciplinary approach in treating patients with CLBP. However, while having incurred a clinically meaningful improvement, these individuals would still be considered to have 'Severe Disability' according to interpretation criteria [18].

From Figure 2 (pg. 108): The majority of the study participants enrolled in this study demonstrated improvement on ODI from baseline to 12-month follow-up. At least the 15 most disabled participants at baseline all demonstrated improvements in outcome at 12-month follow-up, with the most highly disabled individual at baseline improving their score by ~20 points which is highly meaningful from a clinical perspective.

From Table 3 (pg. 108): Multivariate analysis revealed that both being employed at baseline and being 'disabled' at baseline (i.e. ODI >22) were statistically significant predictors of improved outcome (i.e. ODI ≤22)

at 12-month follow-up. From the analysis it appears that if someone is 'disabled' (>22) at baseline, their odds of developing a successful outcome (ODI ≤22) are less than the odds of developing a successful outcome for participants with ODI scores ≤22 at baseline. This is signified by having an Odds Ratio of <1. This implies that those individuals whom are more disabled at baseline are indeed less likely to achieve successful outcome compared with those who are less disabled. The CI of 0.92-0.97, while signifying statistical significance for baseline ODI score, is also very narrow, demonstrating that these findings are not only significant but quite accurate and therefore can be trusted. The odds ratio of 3.61 for baseline employment signifies that those who are employed at outcome have odds that are 3.6 times higher for achieving successful functional outcome (i.e. ODI ≤22) at 12-month follow-up compared with those who are unemployed at baseline. Those who are employed at baseline may more than likely be less disabled than those who are unemployed at baseline, which could very well contribute towards such results. The relatively narrow CI 1.80-7.26 demonstrates both the statistical significance and accuracy of these findings.

From Table 4 (pg. 109): The original multivariate analysis findings were run through a secondary population of randomized study participants (n=262). From this data it was demonstrated that both baseline ODI score >22, and baseline employment can be verified predictors of successful clinical outcome in this cohort of CLBP patients (n=524). These secondary analyses are rare in prospective cohort studies, and thus significantly contributes to the internal validity of the study findings. In this secondary population as with the initial population, individuals with baseline disability (ODI>22) had worse odds for developing successful outcome compared with those who were less disabled at baseline (OR=0.92). The confidence interval of 0.89-0.94 also demonstrates that these findings are both statistically significant and quite accurate. Individuals in this secondary population who were employed at baseline had odds that were 6.3 times higher for developing successful clinical outcome at 12-months compared with those who were unemployed (OR=6.29). While the confidence interval for baseline employment is a little less precise than with the original model (CI 1.96-13.7), it is not so wide that it would be considered inaccurate. From the results of the original and secondary analyses, one can be confident that both baseline employment and baseline disability (ODI >22) are predictive of clinically important outcome in disability at 12-months in CLBP patients undergoing a multi-disciplinary conservative treatment intervention.

Applicability of Study Results

This study was moderately relevant to my clinical question, as it did explore the predictive effects of baseline ODI scores in a cohort of LBP patients, however it did not address whether or not these baseline ODI scores were predictive of future opioid use. Some of the issues limiting the relevance to my clinical question include the study demographic that averaged ~45 years old, compared with the clinical scenario of a 25 year old. The demographic was also mixed in gender, with the majority of participants being female (~58%), compared with the clinical scenario involving only males. While nearly 70% of the study population was working during participation in the study, the authors did not disclose what kinds of work these people were partaking in, and so whether or not any of the population was working in the military setting is unknown. These differences call into the question the external validity of using the study findings with the clinical question population. The study also used a very particular multi-disciplinary conservative approach to treating this cohort of CLBP participants, so whether or not the results could apply to other multi-disciplinary conservative approaches that include physical therapy is called into question.

While these study findings would not be helpful in directly answering the clinical question, they may be helpful in projecting outcome in a patient who presents to clinic with complaints of low back pain, especially if that individual is experiencing chronic low back pain symptoms. Use of the ODI as a self-report screening tool could be helpful in predicting whether or not a patient would benefit from a conservative approach to treatment, as with physical therapy.

As it relates more specifically to the clinical question/scenario, if the military patient comes into the clinic, scores within the mild to moderate range on the ODI, and is active military or is working to some capacity, it may be more likely that this individual would achieve a clinically meaningful improvement in perceived disability at 12-months with a conservative approach to treatment. While the study results do not specifically discuss future opioid use, it could be deduced that individuals experiencing less disability at 12-months would also be experiencing less pain, and would thus be less likely to continue to use opioid medications. In this way, baseline ODI score could be used to indirectly predict potential long-term opioid use, especially if the individual is suffering from more of chronic form of LBP. However since these assumptions were not validated in the study, whether or not they hold true requires further investigation.

Regardless of whether or not the ODI is predictive of future opioid use, this measure should be used in this clinical scenario, as this measure is inexpensive, efficient, reliable, valid, and is considered to be the "gold standard" for assessment of LBP [16].

SYNTHESIS AND CLINICAL IMPLICATIONS

Evidence Synthesis

The evidence suggests that severe perceived disability at baseline on patient self-report measures and/or increased opioid use during the first 3-months after lower back injury are predictive of increased disability and/or opioid use at 12-months. While neither of the studies directly explored whether baseline ODI scores were predictive of future increased opioid use, the study by Van Hooff et al. demonstrated that baseline ODI scores were predictive of 12-month disability in a cohort of CLBP patients [5]. These findings indicate that more severely disabled individuals at baseline are more likely to continue to be disabled at 12-months. The study by Franklin et al. demonstrated that increased perceived baseline disability on the RDQ, and/or increased opioid use during the first 3-months after low back injury were highly predictive of continued opioid use at 12-months [8]. While this study did not explore the effects of a prior history of opioid use in predicting future use, its findings do suggest that patients whom present to clinic with an increased perception of disability and/or whom are taking higher doses of opioids at baseline may be more likely to continue to use opioids for long periods of time, placing them at increased risk for developing dependency and other related complications [20]. While neither study directly answered the components of the clinical question, it is clear that at least moderate evidence exists that suggests that both baseline opioid use and disability are related to future opioid use, and should thus be considered when treating patients with LBP. The applicability of these study findings to the clinical question population is called into question due to the differences between this population, and the study participant populations. Study participants were significantly older (42.4 vs. 25 years), of mixed gender (55% male, 45% female), and presumably none were active military members.

Clinical Implications

Secondary to the severity of complications associated with long-term opioid use for chronic non-cancer pain, it is important for clinicians to understand and potentially screen for factors that are associated with increased risk for longer-term use [20]. The proper identification of these factors can aid clinicians in guiding patient education with regards to alternative forms of pain management, as well as in justifying patient referral should concern arise for the patient's well-being. While certainly not definitive, evidence from the Van Hooff et al. and Franklin et al. studies seem to suggest that severe baseline perceived disability, and/or increased opioid use after onset of LBP symptoms are predictive of increased disability and/or continued opioid use at 12-months [5,8]. Therefore patients presenting to the clinic with LBP symptoms should be screened using either the Oswestry Disability Index or the Roland-Morris Disability Questionnaire [10,17]. Patients who are assessed as being more severely disabled at baseline on either of these measures may be at increased risk for continued disability or continued long-term opioid use, and should be monitored accordingly. Similarly, dichotomous screening of opioid use at baseline should also take place. If the patient is found to be taking opioids, it may be indicated to estimate the approximate MED/quarter based upon the patient's prescribed dose/day as described above. Should it be found that the patient is taking >900 mg/quarter, they may be at relatively increased risk for continued opioid use at 12-months. Like those reporting severe baseline disability, these patients should be monitored closely for changes in patient presentation or signs and symptoms associated with increased opioid use.

Future Research/Research Implications

As no studies were found which explored the ability of prior opioid use or baseline ODI scores in predicting future opioid use, it is recommended that future research explore these areas. Studies should be prospective in nature, and include large homogenous study populations to increase the internal validity of the study findings. As was performed in each of the two studies analysed, multivariate regression analysis of odds ratios should be used to better control for additional variables associated with long-term opioid use. Further because no studies were found that explored either of these factors in a military population, it is also recommended that future research validate the predictive ability of baseline ODI scores and/or prior opioid use in said populations, as military veterans have been found to be nearly twice as likely to die from opioid overdose when compared with the general US population [21]. Additionally, other predictive factors for increased opioid use in patients presenting to physical therapy clinics should be explored in the literature. Understanding these factors and staying out ahead of opioid dependence with alternative pain management education and counselling could be an effective strategy for reducing the impact of the current opioid epidemic.

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